REMARKS

Applicant has not added, cancelled, or amended claims herein.

Rejection Under 35 U.S.C. §112, Written Description

In the August 4, 2009 Office Action issued in connection with the above-identified application the Examiner maintained the rejection of claims 89-105 as allegedly containing subject matter not described in the specification so as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner quoted various parts of the specification but, notably, did not quote one of the paragraphs cited by applicant which actually recites a 10mg dose. For convenience, applicant repeats the paragraph herein:

> "[0011] Oxandrolone disposition and metabolism in man has been studied following oral administration of a 10 milligram dose. The study indicated that oxandrolone was rapidly and completely absorbed, yielding a mean peak plasma concentration of 417 micrograms of oxandrolone per milliliter at 66 minutes. The plasma concentration of oxandrolone declined in a biphasic manner with a distribution half-life of approximately 30 minutes and an elimination half-life of 9.4 hours. Protein binding of oxandrolone was observed to be extensive." (emphasis added)

In addition, the specification states with regard to the nature of the dosage form:

> "[0016] For purposes of administration in accordance with this invention, the active ingredient oxandrolone is combined with solid or liquid pharmaceutical carriers and formulated in unit dosage form using pharmacologically acceptable excipients, or dissolved or suspended in physiologically acceptable solvents or liquid vehicles for oral, percutaneous, or topical administration." (emphasis added)

Furthermore, the specification states with regard to the amount of oxandrolone in the daily dose:

> "[0017] The overall daily dose of oxandrolone to provide a therapeutically effective amount in accordance with the method of this invention can be as low as about 2.5 milligrams and as high as about 20 milligrams, depending upon the patient's response and the mode of administration."

In addition, the specification states with regard to administration of the oxandrolone as a daily dose that:

> "[0021] The route of administration can be oral, percutaneous, transdermal, sublingual, buccal, intravenous, intramuscular, or the like. Of these, oral administration is preferred. The patient's daily dose of the active ingredient preferably is in the range of about 7.5 milligrams, but may exceed 20 milligrams based on clinical response. This daily dose can be given in tablet form as a single dose, or as plural divided doses, preferably 2 to 3 divided doses. The requisite daily dose can also be supplied continuously, for example, by a transdermal patch worn by the patient or intravenously. If the oxandrolone is administered orally, dosages in the range of about 2 to about 5 milligrams three

to four times daily typically may be utilized." (emphasis added)

One skilled in the art is thus apprised by the specification of a "10 milligram dose", a dose that falls within the daily dose range described in the specification, and which, as a daily dose, can be a "unit dosage form" which can be give as "a single dose" and which can comprise "pharmacologically acceptable excipients".

Accordingly, it is not tenable to maintain that the specification does not reasonable convey to one skilled in the art the claimed "unit dosage form comprising a pharmaceutically acceptable carrier and 10 mg of oxandrolone per unit dosage form".

Applicant further notes that in the August 4, 2009 Office Action the Examiner has cited paragraphs of the specification and emphasized, in bold italics, particular passages and sentences. However, the identification by the Examiner of the disclosure of other unit dosage forms in the specification does not detract from, or preclude, the written description for the claimed form. Moreover, the Examiner asserts, and applicant agrees, that "Disclosed Examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments" *In re Susi*, 440 F.2D 442, 169 USPQ 423 (CCPA 1971).

Accordingly, applicant respectfully submits the invention recited in the pending claims is fully described in the subject application and respectfully requests reconsideration and withdrawal of this ground of rejection.

With regard to the Examiner's continued citing of *Fujikawa v. Wattanasin*, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) and *In re Ruschig*, 154 USPQ 118, 123 (CCPA 1967) in respect to the written

description rejection, as applicant has previously pointed out (and regardless of the subject matter of the cases which the Examiner has dismissed as not germane to the holdings of the cases), the cases concern wherein the specific species were not recited in the specification, and the courts indicated that there were no "guides" or "blaze marks" to direct one skilled in the art to the claimed species. In contrast, applicant's presently claimed "10mg" is literally supported, not merely disclosed by genus. Finally, unlike the hundreds or thousands of different species covered by the genus recited in each of the two cases cited by the Examiner, the subject application recites only a few species, including 10mg.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 88-105 under 35 U.S.C. §103(a) as allegedly obvious over Metcalf et al. (of record) in view of ANAVAR® (of record) and Babu et al. (U.S. Patent No. 5,073,380) and "further in view of applicant's admission at page 7." Also, in regard to applicant's submission of Declaration under 37 C.F.R. §1.132 by Dr. Faith Ottery provided as Exhibit 1 of applicant's Communication filed on May 15, 2008, which described, *inter alia*, pill burden and patient compliance problems, suggesting against a 10mg unit dosage form over the Examiner's statements of motivation to make a 10mg unit dosage form for uses of over 10mg a day, the Examiner has declared the position set forth by applicant is not persuasive in that "'pill-burden' issues are not sufficient to rebut the *prima facie* case of obviousness, as a [mere] change of size, [or] shape of a subject matter would not make the subject matter patentably [distinguishable] citing *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) and *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

As the MPEP makes clear in §2144.04, the cited cases apply when trying to patentably distinguish over a prior art product by a change in size or shape. Applicant is not asserting patentably over the prior art based on size or shape, and accordingly the cited cases are not relevant. Moreover, as specified at the beginning of MPEP §2144.04, "As discussed in MPEP §2144, if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. Examples directed to various common practices which the court has held normally require only ordinary skill in the art and hence are considered routine expedients are discussed below. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection." However, as the facts are not similar, the Examiner cannot use this is a basis for discounting the Declaration.

The Examiner does state, in section 9 of the Office Action, that "the cited reference as a whole, teach that the daily dosage of oxandrolone may be 10mg, 20mg, 30mg, or more". The Examiner further asserted that it would therefore have been obvious to make 10mg unit dose. However, Metcalf et al. make it clear that doses under 30mg per day were less effective than doses over 30-150 mg per day doses. Thus, one skilled in the art would not chose a 10mg dose, but a 30 mg or greater dose. Also in light of patient compliance and pill burden issues the obvious unit form dose in light of Metcalf would be a 30mg or greater unit dose form.

With regard to the Examiner citing that "Disclosed examples and preferred embodiments do not constitute a teaching away from a

broader disclosure or nonpreferred embodiments" it is noted that Metcalf et al. does not teach a 10mg unit dosage form as either part of "a broader disclosure" or as a "nonpreferred embodiment", and thus the citation is not relevant. In addition, the citation of *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2D 1130, 1132 (Fed. Cir. 1994) for the proposition that "A known or obvious composition does not become patentable because it has been described as somewhat inferior to some other product for the same use" (emphasis added) is also irrelevant because (1) a 10mg unit dosage form has not been described and (2) it was the 2-30mg daily doses, and not 10mg unit dosage form, which are described in Metcalf et al. as inferior to 30-150mg doses. Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.